UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,217	12/04/2003	Mark Roby	2881	7985

7590 06/01/2007

Patent Counsel
United States Surgical, a division of
TYCO HEALTHCARE GROUP LP
150 Glover Avenue
Norwalk, CT 06856

EXAMINER	
SANDERS, KRIELLION ANTIONETTE	
ART UNIT	PAPER NUMBER
1714	

MAIL DATE	DELIVERY MODE
06/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,217	ROBY, MARK	
	Examiner	Art Unit	
	Kriellion A. Sanders	1714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *9-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-8, in the reply filed on 10/20/06, is acknowledged. The traversal is on the ground(s) that a search for the invention of Group I would recover the invention of Group II. This is not found persuasive because applicant's claims suggest a composition that has an "intended use". However, that composition may be found useful for other applications. Therefore contrary to applicant's argument a search for the invention of Group I would not necessarily recover the invention of Group II. The inventions of Groups I and II are related as product and process of use and have been shown to be separate and distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9- 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/20/2006.

2. This application contains claims 9-26 drawn to an invention nonelected with traverse in the reply filed on 10/20/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1 and 3-8 are rejected on the ground of nonstatutory double patenting over claims 1-12 of U. S. Patent No. 6,878,757 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Each invention claims coatings for sutures comprising epsilon-caprolactone and metal salts of a fatty acid ester.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

U.S. Pat. No. 6,878,757 to Roby describe antimicrobial coatings applicable to sutures where the coating comprises (i) mixtures of caprolactone copolymers and silver stearate, and (ii) mixtures of copolymers of epsilon-caprolactone, bioabsorbable monomer and sodium stearoyl lactylate or the silver salt of stearoyl lactylate, respectively. The silver salt in both of these references remains in a salt form in the copolymer matrix, and silver ions are released into a

target environment from the coating by solubilization of the silver salt in the target environment. In turn, the solubility of the silver salt is a function of the nature of environment where it is delivered, and factors such as counter-ion concentration and ionic strength of the target environment.

Response to Arguments

5. Applicant's arguments filed 3/9/07 have been fully considered but they are not persuasive. The rejection is maintained absent the filing of an acceptable terminal disclaimer.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roby et al., US Patent No. 5,716,376, in view of Mattei, U.S. Pat. No. 4,201,216.

Roby et al discloses a coating for absorbable surgical articles that may be formed from a mixture of a caprolactone-derived copolymer in admixture with an ester of a fatty acid.

Suitable monomers which can be copolymerized with epsilon-caprolactone include alkylene carbonates such as trimethylene carbonate, tetramethylene carbonate, dimethyl trimethylene carbonate; dioxanones; dioxepanones; absorbable cyclic amides; absorbable cyclic ether-esters derived from crown ethers; hydroxyacids capable of esterification, including both alpha hydroxy acids (such as glycolic acid and lactic acid) and beta hydroxyacids (such as beta

hydroxybutyric acid and gamma hydroxyvaleric acid); polyalkyl ethers (such as polyethylene glycol and polyloropyline glycol and combinations thereof; with glycolide being a preferred monomer.

Particularly useful fatty acid esters for purposes of formulating the composition include calcium, magnesium, aluminum, barium, or zinc stearoyl lactylate; calcium, magnesium, aluminum, barium, or zinc palmityl lactylate; calcium, magnesium, aluminum, barium, or zinc olelyl lactylate; with calcium stearoyl-2-lactylate. The bioabsorbable mixture of the invention may be applied to a suture by any suitable process. See col. 1, line 14 through col. 2, line 67.

Mattei discloses a glycolide/lactide copolymer blended with calcium stearate as a suture coating. The patented invention provides for a coating for sutures, particularly synthetic absorbable multifilament sutures. The suture coating comprises an absorbable composition of a film-forming polymer and a substantially water-insoluble salt of a C_6 or higher fatty acid. The coating is preferably applied to the suture from a solvent solution to provide a final coating add-on of from about 2 to 10 percent by weight of the suture.

The film-forming polymer is preferably a copolymer of lactide and glycolide, while the fatty acid salt is preferably a calcium salt. The ratio of polymer to fatty acid salt in the coating composition may be within the range of about 1:4 to 4:1 parts by weight. The fatty acid salts useful in the coating compositions of the invention include the calcium, magnesium, barium, aluminum, and zinc salts of the higher fatty acids, particularly those having from about 12 to 22 carbon atoms and mixtures thereof. The calcium salts of stearic, palmitic and oleic acids are particularly preferred for use in the invention. See col. 2, line 51 through col. 5, line 30.

At the time of his invention, Roby et al recognized that metal salts of higher fatty acids were known in the art to be useful in preparing coatings or suture materials. Roby et al states:

> Although calcium stearate was used as a component in the Vicryl suture coating; the manufacture and application of such a suture coating would require an impractical and uneconomical dip coating process because calcium stearate (a hydrophobic metal salt of a fatty acid) generally is insoluble. Therefore, a suture coating fabricated from materials that would dissolve in solution and thus obviate the necessity of using dip coating processes would provide great manufacturing advantages.

Recognizing that there is utility for the metal salts of higher fatty acids, although not without certain limitations, the ordinary practitioner in this art would have found it obvious to utilize these salts in preparation of coatings for sutures, if the associated and required dip-coating process were an acceptable means of manufacture. Additional emphasis is placed on the fact that the caprolactone copolymers of Rody et al are preferably copolymerized with glycolide monomers such as those disclosed by Mattei. Therefore the metal salts of higher fatty acids of Mattei would be expected to function in an equivalent manner in the coatings of Rody et al.

Therefore, in the absence of a showing of unexpected results by utilizing the metal salts of higher fatty acids disclosed by Mattei in the suture coating materials of Roby et al, such a composition is considered obvious.

Response to Arguments

Applicant's arguments filed 3/9/07 have been fully considered but they are not persuasive. Applicant's arguments are not persuasive because Roby et aaaal discloses the essential components of applicant's claimed invention. This includes a copolymer of epsilon-caprilactone and at least one other bioabsorbable copolymerizable monomer, a metal salt of a fatty acid ester and a fatty acid ester such as set forth in applicant's claim 5. Since Roby formulates coating compositions for surgical sutures, it is clear that these components would have been formulated in amounts that would have afforded the required properties to manufacture said sutures.

Mattei is relied upon to teach that the metal stearate salts are known to be used in formulating coatings for surgical sutures wherein said coatings are comprised of polymers of lactide and glycolide. Since the Roby polymers may also be based upon glycolide, it is expected that the stearate salts of Mattei would provide appreciable anti microbial properties to the closely related glycolide/epsilon-caprolactone copolymers of Roby et al. Because Roby et al encompasses the fatty acid metal salts of applicant's claim 1, the rejection is consider proper.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kriellion A. Sanders whose telephone number is 571-272-1122. The examiner can normally be reached on Monday through Thursday 8:30am-7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kriellion A. Sanders
Primary Examiner
Art Unit 1714

ks